

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
31 March 2005 (31.03.2005)

PCT

(10) International Publication Number
WO 2005/027790 A1

(51) International Patent Classification⁷: A61F 2/06, 2/24

(21) International Application Number:
PCT/EG2003/000010

(22) International Filing Date:
23 November 2003 (23.11.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2003090946 24 September 2003 (24.09.2003) EG

(71) Applicant and

(72) Inventor: LOTFY, Wael Mohamed Nabil [EG/EG]; 43
Giza Street, Cairo 12211 (EG).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC,
SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA,
UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (BW, GH,
GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE,
SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

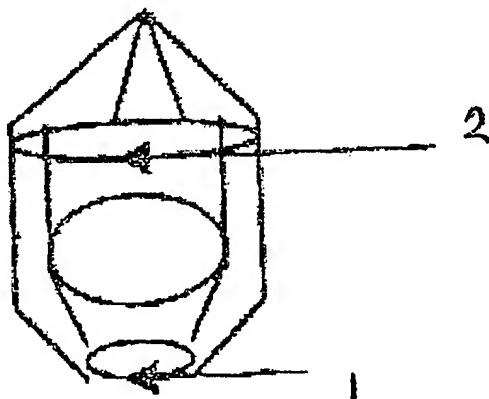
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*
- *of inventorship (Rule 4.17(iv)) for US only*

Published:

- *with international search report*
- *with amended claims*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: VALVED BALLOON STENT



(57) Abstract: This invention is concerned with a valved inflatable balloon stent that is fixed through interventional catheterization to function as a valve e.g. cardiac valve.

WO 2005/027790 A1

Valved Balloon Stent (detailed description):

This invention is concerned with a lined inflatable and dilatable valved balloon stent (the stent is dilatable and its lining is either inflatable or dilatable, the balloon is inflatable and deflatable) that will be introduced inside vessels to function as a valve.

So that the stent is introduced in its smaller size then dilated to take the size of the intended vessel; the balloon will then be inflated with an appropriate material e.g. carbon dioxide, normal saline, air.

Apart from the central balloon the proximal opening can be inflatable. In simpler terms, it's a cage like design mounted on the dilatable stent having a narrower opening on one side and the cage from the other side (the narrowing can be inflatable) and an inflatable ball enclosed. This ball functions as the valve.

Figure 1 demonstrates a sketch of the invention.

For this purpose the metallic dilatable stents in common use in cardiology practice can be modified to this new shape. The balloon moving inside the cage can be prepared from any inflatable and non reactive tissue e.g. similar to valvotomy balloons in common practice.

During placement of this valved balloon stent, the previous damaged non functioning valve can be crushed (putting the new valve in the place of the old one exactly).

This procedure will be done through per catheter intervention in the catheterization laboratory. It will allow emergency as well as permanent valve replacement when other options are worrisome.

I expect it thus to revolutionize the practice. Because the ability to perform per catheter inflatable valve replacement without mortality will definitely make surgical corrections of simple as well complicated cardiac lesions be not needed or at least deferrable to the time where they could be done with less mortality.

Previous state of the art:

A surgical procedure is undertaken with its inherent costs, risks and problems to replace the non functioning valve with another human, animal or metallic. Fixing an animal origin valve through catheterization.

Problems in the previous state of the art:

High cost and associated risks of surgical operation for valve replacement.

Non malleability in dealing with the valve after its placement.

5 The high cost of the valve itself.

10 **What is new about this invention?**

Achieve the same result of surgery through interventional catheterization.

Malleability in the dealing with the valve during and after placement.

Avoiding the risks and costs of the surgical or operation.

15

How can it be used ?

20 A selected company producing the common use intravascular stent will be
chosen after agreement with the inventor to upgrade some of its stents with
the new designs and linings I suggested.

25

30

35

40

45

Claims:

1. The addition of inflatable and /or compressible and/or controllable lining to stents (medical or non medical) to function as a valve for the flow of fluids or gases through.
 - a. This includes any form of stents including but not limited to metallic, plastic, totally inflatable stents or otherwise of medical or non medical use.
 - b. This includes all shapes of stent designs including but not limited to ring, tubular, cylindrical, cone, pentagonal ...etc.
 - c. This includes all shapes and materials of linings used for the same purpose including but not limited to Gortex, Teflon, PTFE.
2. The addition of fixed lining narrowing excluding animal native or treated valves to stents (medical or non medical) to function as a valve for the flow of fluids or gases through.
 - a. This includes any form of stents including but not limited to metallic, plastic, totally inflatable stents or otherwise of medical or non medical use.
 - b. This includes all shapes of stent designs including but not limited to ring, tubular, cylindrical, cone, pentagonal ...etc.
 - c. This includes all shapes and materials of linings used for the same purpose including but not limited to Gortex, Teflon, PTFE.
3. Stentless designs used for the same purpose (to function as a valve for the flow of fluids or gases through a vessel). The implantation techniques includes but is not limited to interventional, surgical or endoscopic).
4. The use of this technique includes but is not limited to inside the blood vessels, airways, urinary, gastrointestinal passages or industrial pipes.
5. This includes but is not limited to the design suggested above for this purpose.
6. The designs that will achieve the valve function for the flow inside the vessel in one or more than one direction are included as well.

PCT/EG2003/000010

AMENDED CLAIMS

received by the International Bureau on 08 December 2004 (08.12.04): original claims 1 to 6 have been replaced by amended claims 1 to 16.

From: Lotfy, Wael Mohamed Nabil
43 Giza Street, 12211 Cairo, Egypt
Fax: +202 7493070.

To: International Bureau of WIPO
34 chemin des Colombettes
1211 Geneva 20, Switzerland.
Fax : 41 22 740 14 35.

Subject :
International application number PCT/EG 2003/000010

Claims :

There were originally 6 claims filed, claims 3, 4, 5, 6 are cancelled;
Claim 1 and 2 are unchanged, claims 7 to 13 are added.

7. The ball for the valve mechanism is inflatable by CO₂, air, flowable gelatinous material, metallic powder, radioopaque fluid or hardening agent.
8. The ball for the valve mechanism comprising a check valve for inflation or deflation.
9. The inflatable ball wherein the check valve for inflation is of a breakaway design to permit separation from the means for injecting.
10. The ball for the valve mechanism where the one way valve comprises a plug of an elastomer having a slit through which closes upon application of pressure within the tubing.
11. The ball for the valve mechanism where the ball is linked to the stent by a ribbon of biologically inert material to allow limited mobility of the ball and/or inflation or deflation of the ball alone or with the stent.
12. The ball for the valve mechanism where the ball is separate from the stent.
13. The ball for the valve mechanism that is modifiable and retrievable after implantation to allow further sizing as needed.
14. The lining of claim 1 and 2 that is fabricated solely or at least partly from a semipermeable membrane, and wherein the hollow wall has disposed hydrophilic material capable of absorbing a liquid to thereby increase the volume of said material. The final shape may be appropriate or modifiable by ballooning from the lumen or by inflation.

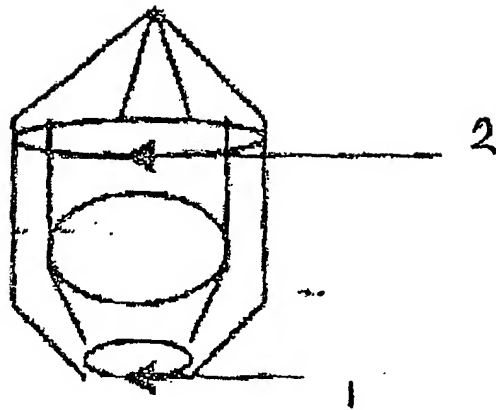
BEST AVAILABLE COPY

AMENDED SHEET (ARTICLE 19)

15. The lining of claim 14 that is fabricated from a semipermeable membrane, and wherein the hollow wall has disposed hydrophilic material that is a gel.
16. The use of ultrashort stents (whether fixed, balloonable or inflatable) i.e. rings to support the valve mechanism instead of usual stents.

Wael Lotfi

AMENDED SHEET (ARTICLE 19)



CLASSIFICATION OF SUBJECT MATTER

IPC⁷: A61F 2/06, 2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC⁷: A61F 2/04, 2/06, 2/24 // A61M 29/02

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2003/047468 A1 (PERCUTANEOUS VALVE TECHN.) 12 June 2003 (12.06.2003) <i>abstract; figures 1, 17a, 17b, 20a - 23e, 40a, 43a; page 3, 4th par. - last par.; page 4, 3rd and 4th par.; page 7, 4th - 6th par.; page 20, 5th par.; page 21, 2nd-4th par.; page 22, 4th and 5th par.; page 30, last par.; page 32, 5th and 6th par.; page 33, 3rd par.; page 42, 3rd par.; page 44, 2nd par.</i>	1
A		2
X	EP 1057460 A1 (NUMED INC.) 6 December 2000 (06.12.2000) <i>the whole document.</i>	1
A		2
A	US 6293968 B1 (S.TAHERI) 25 September 2001 (25.09.2001) <i>figure 5; column 6, lines 39-46.</i>	2

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

„A“ document defining the general state of the art which is not considered to be of particular relevance

„E“ earlier application or patent but published on or after the international filing date

„L“ document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

„O“ document referring to an oral disclosure, use, exhibition or other means

„P“ document published prior to the international filing date but later than the priority date claimed

„T“ later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

„X“ document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

„Y“ document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

„&“ document member of the same patent family

Date of the actual completion of the international search

19 October 2004 (19.10.2004)

Date of mailing of the international search report

29 October 2004 (29.10.2004)

Name and mailing address of the ISA/AT

Austrian Patent Office
Dresdner Straße 87, A-1200 Vienna

Facsimile No. 1/53424/535

Authorized officer

LUDWIG H.

Telephone No. 1/53424/340

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EG 2003/000010

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 4
because they relate to subject matter not required to be searched by this Authority, namely:
claim 4 relates to the use of the stent and thus to a method for therapeutical treatment of the human or animal body according to PCT Rule 39.1 (iv) under Article 17(2)(a)(i)
2. ☒ Claims Nos.: 3,5,6
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
claims 3,5,6 do not refer to exactly defined technical features of a stent (".. stentless design used for .."; ".. this includes but is not limited to the different designs .."; ".. the designs that will achieve .."); according to PCT Rule 6.3 (a)(b) claims should contain technical features of the invention which are necessary for the definition of the claimed subject matter
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

Patent document cited in search report			Publication date	Patent family member(s)			Publication date
EP	A	1057460	2000-12-06	CA	A	2297536	2000-12-01
				JP	A	2001000460	2001-01-09
US	B	6293968	2001-09-25	none			
WO	A	20030474 68		none			